

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING,
SALES PRACTICES AND PRODUCTS
LIABILITY LITIGATION

MDL Docket No. 2738

Civil Action No. 16-2738 (MAS) (RLS)

MEMORANDUM ORDER

THIS MATTER comes before the Court upon Plaintiffs’ April 24, 2025, correspondence regarding the U.S. Food and Drug Administration’s (“FDA”) proposed rule, Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products (the “Proposed Rule”). (Pls.’ Correspondence, ECF No. 33755); 89 Fed. Reg. 105490 (Dec. 27, 2024). Plaintiffs request permission from this Court to supplement the record regarding the Proposed Rule, or in the alternative, that this Court take judicial notice of it. (Pls.’ Correspondence; *see id.* at Ex. A.) Plaintiffs contend that the Proposed Rule, which proposes mandatory standardized testing of talc-containing cosmetic products and includes corresponding adulteration provisions, “directly impacts” motions that are pending before this Court, in part because the J&J Defendants (“Defendants”) cite to statements made by the FDA in their *Daubert* motions that are “supersede[d]” by the Proposed Rule. (Pls.’ Correspondence 1.)¹

Defendants oppose Plaintiffs’ request on the grounds that the Proposed Rule is not yet final. (Defs.’ Correspondence, ECF No. 33777.) Should the Court grant Plaintiffs’ request, however,

¹ Plaintiffs do not clearly identify which of Defendants’ *Daubert* motions include a reference to or rely on the FDA’s prior statements. (*See* Pls.’ Correspondence 1.)

Defendants request that the Court also consider public comments critiquing the Proposed Rule,² and permit Defendants to introduce new peer-reviewed scientific literature on this issue. (*Id.*)

Here, the FDA has not completed its formal rulemaking process with respect to the Proposed Rule. (*See* Pls.’ Correspondence at Ex. A.) While Plaintiffs contend that the Proposed Rule “represents the current policy of the FDA,” the Proposed Rule is not final and does not represent final agency action. (Pls.’ Correspondence 1; *see* Defs.’ Correspondence); *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 845 (1986) (“It goes without saying that a proposed regulation does not represent an agency’s considered interpretation of its statute and that an agency is entitled to consider alternative interpretations before settling on the view it considers most sound.”)

Because current regulations govern until the Proposed Rule becomes final, the Court “decline[s] to take cognizance of the proposed regulation.” *Depenbrock v. Cigna Corp.*, 389 F.3d 78, 85 (3d Cir. 2004) (quoting *Ca. Rural Legal Assistance, Inc. v. Legal Servs. Corp.*, 917 F.2d 1171, 1173 n.5 (9th Cir. 1990)); Trial Tr., *Doomey v. Johnson & Johnson et al.*, No. 21-47286, at 4718:06-4719:1 (Cal. Super. Ct. Apr. 16, 2025) (excluding evidence of the same Proposed Rule at trial and stating, “if you have a[n] actual regulation that says A, B, C, and D, and you want to . . . ask him about those FDA specific regulations, then that is fair game to me. . . . But what I don’t want to hear is this document or using this document when . . . it says ‘Proposed Rules.’ . . . It’s not the same thing. . . . If you’re asking about the proposed rules by the FDA . . . what does that mean? It means nothing to me. . . . under [California Evidence Code §] 352, I would exclude it.”).³


² The Proposed Rule was open to public comments until March 27, 2025. (Pls.’ Correspondence at Ex. A.)

³ A copy of this trial transcript can be found at Exhibit A to Defendants’ response. (Defs.’ Correspondence at Ex. A.)

For the foregoing reasons,

IT IS on this 7th day of May, 2025, **ORDERED** that:

1. The Court denies Plaintiffs' request to supplement the record regarding the Proposed Rule (ECF No. 33755).
2. The Court declines to take judicial notice of the Proposed Rule.



MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE